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Yat Sun Or

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YAT SUN OR
APPELLANT

Appeal 2008-3651
Application 10/763,377
Technology Center 1600

Decided: August 25, 2008

Before RICHARD E. SCHAFER, SALLY GARDNER LANE, and
JAMES T. MOORE, *Administrative Patent Judges*.

LANE, *Administrative Patent Judge*.

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal is from a Final Rejection of claims 1-12, which are all of the pending claims. 35 U.S.C. § 134. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

The application was filed January 23, 2004. The real party in interest is said to be Enanta Pharmaceuticals, Inc. (App. Br. 1).

The Examiner relied on international patent application publication WO 99/21864 ("Or"), which was published on May 6, 1999. Appellant did not argue against the prior art status of this reference.

Appellant appealed the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, and claims 1-12 under 35 U.S.C. § 103(a) over Or. Appellant did not argue for the patentability of any of the claims separately. We review claim 1 as a representative claim. 37 C.F.R. § 41.37(c)(1)(vii).

II. FINDINGS OF FACT

The record supports the following findings of fact as well as any other findings of fact set forth in this opinion, by at least a preponderance of the evidence.

1. Appellant's claim 1 recites:

A process comprising the step of
reacting a macrocyclic compound
characterized by at least two nucleophilic moieties
with a bifunctional bridging component
characterized by its ability to form π -allyl metal complex
in the presence of catalyst
thereby achieving a bridged macrocyclic product.

(App. Br., Claims Appx. 8).

2. Appellant's specification provides that "[p]referred macrocyclic compounds useful in the process of the present invention are macrolides." (Spec. 3, ll. 1-2).

3. Appellant's specification provides:

Macrocyclic compounds useful in the process of the present invention are cyclic compounds comprising at least 7 ring atoms selected from carbon, nitrogen, oxygen, sulfur, silicon, phosphorous, or other atoms, wherein each ring atom may optionally be substituted with oxygen, and each macrocyclic

compound may optionally contain one or more degrees of unsaturation (double or triple bonds). It is understood that the macrocyclic compounds useful in the present invention can be multicyclic, such as bi- or tricyclic.

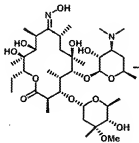
(Spec. 2, ll. 20-25).

4. Appellant's specification provides that

[m]acrolide antibiotics play a therapeutically important role, particularly with the emergence of new pathogens. Structural differences are related to the size of the lactone ring and to the number and nature (neutral or basic) of the sugars. Macrolides are classified according to the size of the lactone ring (12, 14, 15 or 16 atoms). The macrolide antibiotic family (14-, 15- and 16-membered ring derivatives) shows a wide range of characteristics (antibacterial spectrum, side effects and bioavailability).

(Spec. 1, l. 32, through 2, l. 1).

5. Appellant's specification provides the compound



as an operable macrolide in Example 1. (Spec. 25). Appellant provided other macrolides as operable embodiments in other Examples. (Spec. 25-35).

6. Or teaches a process for preparing bridged erythromycin compounds. (Or abstract).

7. Erythromycin is a macrolide within the scope of Appellant's claimed process. (Spec. 3, ll. 1-3).

8. It is not contested that “Scheme 3” of Or teaches preparation of bridged erythromycin compounds using a bridging component, $\text{H}_2\text{N}-(\text{CH}_2)_m\text{-A-B-D-X}$ and $(\text{CH}_2)_2\text{-C}=\text{CH}_2$, which forms a π -allyl metal complex. (Or 36; see Reply Br. 7).

9. Or teaches use of the catalyst Pd(II) or Pd(O). (Or 32, ll. 1-4).

III. LEGAL PRINCIPLES

“During examination, ‘claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.’” *In re American Academy of Sci. Tech. Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (quoting *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990)).

The first paragraph of 35 U.S.C. § 112 requires that a claimed invention be “enabled” by the specification, wherein “the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .” are disclosed. See *Ex parte Bhide*, 42 USPQ2d 1441, 1448 (BPAI 1996) (“A specification which contains a statement of the manner and process of using the invention in terms which correspond in scope to those used in defining the subject sought to be patented *must* be taken as in compliance with the “how to use” requirement of the first paragraph of 35 U.S.C. Section 112 *unless* there is a reason to doubt the objective truth of the statement.”).

“Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation.” *In re*

Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988). “[A]ppellants are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art such as the present [chemical] record presents” *In re Angstadt*, 537 F.2d 498, 503 (CCPA 1976). Indeed, it is the nature of the experimentation required to enable the full scope of a claim, not the quantity of experimentation, which is important. In *Angstadt*, the court stated:

appellants have supplied the list of catalysts and have taught how to make and how to use them, we believe that the experimentation required to determine which catalysts will produce hydroperoxides would not be undue and certainly would not “require ingenuity beyond that to be expected of one of ordinary skill in the art.” [citation omitted]

Id. In addition, the court specifically rejected that “the disclosure must provide ‘guidance which will enable one skilled in the art to determine, *with reasonable certainty before performing the reaction*, whether the claimed product will be obtained’ (emphasis in original). . . .”

Id.

“Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. . . . Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid.” *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “If the rejection under § 102 is proper,

however, appellant cannot overcome it by showing such unexpected results or teaching away in the art, which are relevant only to an obviousness rejection.” *In re Malagari*, 499 F.2d 1297, 1302 (CCPA 1974).

IV. ANALYSIS

Rejection under 35 U.S.C. § 112, first paragraph

Appellant’s claim 1 recites:

A process comprising the step of reacting a macrocyclic compound characterized by at least two nucleophilic moieties with a bifunctional bridging component characterized by its ability to form π -allyl metal complex in the presence of catalyst thereby achieving a bridged macrocyclic product.

(FF¹ 1). Appellant’s specification provides some of the characteristics of the macrocyclic compounds, wherein

[m]acrocyclic compounds useful in the process of the present invention are cyclic compounds comprising at least 7 ring atoms selected from carbon, nitrogen, oxygen, sulfur, silicon, phosphorous, or other atoms, wherein each ring atom may optionally be substituted with oxygen, and each macrocyclic compound may optionally contain one or more degrees of unsaturation (double or triple bonds). It is understood that the macrocyclic compounds useful in the present invention can be multicyclic, such as bi- or tricyclic.

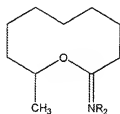
(FF 3). Appellant’s specification also provides that “[p]referred macrocyclic compounds useful in the process of the present invention are macrolides.”

(FF 2). Indeed, our understanding is that the products of the invention are useful as macrolide antibiotics. (FF 4). Claims are given their “broadest reasonable interpretation consistent with the specification,” during

¹ Finding of Fact.

examination, *see American Academy, supra*, thus, Appellant's claim 1 encompasses macrolides, as well as macrocyclic compounds that are not macrolides.

The Examiner rejected the process recited in Appellant's claim 1, asserting that it "does not reasonably provide enablement for a process using any macrocyclic compound." (Ans. 3). In support, the Examiner provided



the compound as an inoperative species of the claimed genus. The Examiner asserted that

any macrocycle with a nucleophilic moiety as broadly encompassed, will not form a bridge via the reaction as instantly claimed. The instant specification is enabling only for macrolides like erythromycin having functional groups, for example, hydroxyl (with a lone pair of electrons on oxygen), which will form the said bridge. In cases where the formation of such a bridge is hard to predict is when one of skill in the art will have to perform undue experimentation to see if the bridge formation is possible.

(Ans. 7). Appellant agreed, noting that "[i]t is undisputed that the structure presented by the Examiner cannot form a bridge." (App. Br. 3). Appellant argued, though, that "[a] skilled person in the art can easily determine which embodiments would be inoperative or operative following the instant claimed process without undue experimentation." (App. Br. 3-4). Furthermore, Appellant argued that "[a]s the claims only embrace processes which achieve a bridged macrocyclic product, it is not believed that the claims embrace any inoperative embodiments." (Reply Br. 6).

According to the Examiner, “[o]ne of ordinary skill in the art would have to carry out the process in order to determine the type of macrocyclic compound and the type of nucleophilic moiety and the type of catalyst needed to carry out the said process.” (Ans. 5).

We presume that the specification provided sufficient information to allow those in the art to determine which compounds could form a bridge. *See Bhide, supra*. The Examiner did not explain why carrying out the process to make the determination would have necessitated undue experimentation. The Examiner did not point to any portion of this process that would not have been routine for those of skill in the art. *See Wands, supra; see also Angstadt, supra*.

Furthermore, the Examiner failed to demonstrate that there are a large number of inoperable macrocyclic compounds. *See Atlas Powder, supra*. Finally, we understand the structure of the inoperative macrocyclic compound provided by the Examiner and the structure of an operative macrolide provided by in the specification (*see* FF 5) to be very different. The Examiner did not explain why those in the art would not have been able to readily ascertain which structures within the scope of the claimed genus would form a bridge and which would not.

Accordingly, we reverse the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Rejection under 35 U.S.C. § 103(a)

Or teaches a process for preparing a bridged erythromycin compound (FF 6), which is a macrolide within the scope of Appellant’s claimed process. (FF 7). The Examiner asserted that the process taught by Or involves two different bridging components. (Ans. 7-8). Appellant agreed

that it “is true that the macrocycles and one of the bridging components disclosed by [Or] fall into the definitions [of] macrocyclic and bridging component of the presently claimed invention” (Reply Br. 7). Or also teaches use of catalysts in the disclosed process. (FF 9).

Appellant argued that

[t]he bridged macrocyclic product in the prior art process can not be formed following the process stated in claim 1. The bridged macrocyclic product in the prior art can only be achieved with further chemical modification(s). It is clear that the use of only the second component containing a double bond capable of forming a pi-allyl metal complex disclosed in [Or] do not meet all the limitations of claim 1 of the present invention.

(Reply Br. 7-8). However, claim 1 uses the term “comprising,” which allows for other steps to be included in the process. Therefore, we conclude “further chemical modification(s)” are not excluded from the claims. Consequently, we do not agree that the process in the prior art is not anticipatory.

Appellants argued that “taking the two bridging components and then coupling them prior to bridging does not in fact reduce the number of steps” (App. Br. 5) and that

the process suggested by the Examiner would be expected to reduced efficiency based on the possible side reactions. . . . It is not clear how a process that would be expected to lower the overall yield resulting from complex mixtures can make obvious the claimed process, which resulted in a very high yield.

(*Id.*). Appellant did not direct us to evidence in support of these assertions. “Argument of counsel cannot take the place of evidence lacking in the

record.” *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977). Thus, we are not convinced by these arguments.

Accordingly, Or anticipates the claimed process. “It is well settled that ‘anticipation is the epitome of obviousness.’” *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (citations omitted). Thus, we do not find error in the Examiner’s rejection of claim 1 under 35 U.S.C. § 103(a).

VI. ORDER

Upon consideration of the record and for the reasons given, the Examiner’s rejection of claim 1 under 35 U.S.C. § 112, first paragraph, is REVERSED; and

the Examiner’s rejection of claims 1-12 under 35 U.S.C. § 103(a) over Or is AFFIRMED.

AFFIRMED

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